

REMARKS

This is in response to the Office Action mailed April 15, 2008, in which the Examiner rejected claims 277, 279-286, 288-301, 316 and 317. Applicant has amended claim 277 and canceled claim 316. Entry of the amendment and reconsideration of the application, as amended, is respectfully requested.

Claim Amendments

Claim 277 has been amended to delete "having a medical functionality" and claim 316 has been canceled. The amendments are believed to either place the application in condition for allowance or in better condition for appeal. Entry of the amendments is respectfully requested.

Finality of Rejections

In the Office Action mailed April 15, 2008, the Examiner made the rejections final because "Applicant's amendment necessitated the new ground(s) of rejection . . ." Applicant respectfully disagrees with this finding.

In the Office Action mailed August 7, 2007, the Examiner rejected claim 277 as being anticipated by U.S. Patent No. 2,816,997 (Conrad) and U.S. Patent No. 5,037,488 (Wienand). Additionally, the Examiner indicated that claim 278 would be in condition for allowance if presented in independent form. In response to the Office Action, Applicant submitted an Amendment (May 21, 2007) that re-wrote claim 278 in substantially independent form as independent claim 277. As a result of Applicant's reliance on the Examiner's statement that claim 277, as amended, would be in condition for allowance, Applicant did not rebut the Examiner's rejections of claim 277.

However, in the Office Action mailed August 7, 2007, the Examiner rejected the amended claim 277 as being obvious in view of Conrad and U.S. Patent No. 5,984,711 (Woodard). In Applicant's response mailed December 5, 2007, Applicant amended independent claim 277 to place it in substantially the same form as presented prior to the amendment of May 21, 2007. Additionally, Applicant re-presented canceled claim 278 as new claim 317. These amendments

placed the claims in substantially the same condition they were in prior to the amendment of May 21, 2007. Applicant then presented arguments that the claims were allowable in view of the cited references.

Applicant does not believe that the amendment to independent claim 277 submitted December 5, 2007 necessitated a new search by the Examiner. The amendment resulted in the broadening of claim 277. By definition, any art that the Examiner construed as “reading on” claim 277 prior to the amendment, would necessarily read on the claim after it had been broadened. Thus, the Examiner’s search was not necessitated by Applicant’s amendment submitted December 5, 2007.

In light of the above, Applicant requests that the Examiner reconsider the finality of the rejections.

Claim Rejections – 35 U.S.C. §112

In the Office Action, the Examiner rejected claims 277, 279-286, 288-301 and 317 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Although Applicant believes that claim 277 satisfies 35 U.S.C. §112, second paragraph, for the reasons set forth below, Applicant requests entry of the amendment to independent claim 277, in which the phrase “having a medical functionality” has been deleted. The amendment to claim 277 will operate to either place the application in condition for allowance or in better condition for appeal.

In the event that the Examiner refuses entry of the amendment to claim 277, Applicant respectfully believes that the language “medical functionality” is sufficiently clear to those of ordinary skill in the art to satisfy 35 U.S.C. §112, second paragraph. The plain meaning of the phrase “medical functionality” is something that serves a medical function. This meaning is consistent with use of the term in claim 277 to describe the “implantable circuitry”, which is a component of a “Medical apparatus for placement in a patient”.

Further, the specification describes embodiments of the connection system 120 (FIGS. 3A

and 3B), to which claim 277 is directed, as having uses with implantable circuitry having a medical functionality, such as measuring physiological parameters of a patient. For instance, the connection system 120 is described as being used with the implantable pressure sensor (FIG. 1), which is configured to measure a pressure within the body of a patient (see paragraph [0110] of U.S. Pub. No. 2004/0152999). The specification also states in paragraph [0110] that

It is to be understood, however, that the apparatus and methods described with reference to FIGS. 3A and 3B could alternatively or additionally be applied with a range of circuitry, such as, for example, a signal processor such as a microprocessor, sensors, such as pressure sensors other than those described herein, temperature sensors, chemical sensors (e.g., glucose sensors), flow sensors, or sensing electrodes. Further alternatively or additionally, connection system maybe be used in combination with active elements, such as, by way of illustration and not limitation, actuators, stimulating electrodes, electroactive polymers, or light sources for photodynamic therapy.

These examples of implantable circuitry, with which the connection system 120 may be used, are known by those skilled in the art to be useful in performing a medical function and, thus, have “medical functionality”.

For at least these reasons, claim 277, as previously presented, satisfies 35 U.S.C. §112, second paragraph. Accordingly, Applicant requests that the rejection be withdrawn.

Claim Rejections – 35 U.S.C. §103

The Examiner rejected pending claims 277, 288 and 291-301 under 35 U.S.C. §103(a) as being unpatentable over Dickenson (U.S. Patent No. 5,508,476 A), in view of Itoigawa et al., (U.S. Patent No. 5,807,265 A). Applicant respectfully believes that the rejections can be withdrawn for the reasons set forth below.

With regard to independent claim 277, the Examiner found Dickenson to teach all of the elements of claim 277 except that Dickenson relates to a mounting arrangement for semiconductor devices rather than the medical apparatus of claim 277. However, the Examiner found Itoigawa to teach a medical apparatus for placement in a patient that includes “a semiconductor pressure chip/circuitry 6”. The Examiner concluded that it “would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Dickenson’s semiconductor device to

be a semiconductor pressure sensor chip as taught by Itoigawa because Dickenson provides fatigue-free external connections to a device.” Applicant respectfully disagrees with these findings.

Dickenson relates to mounting arrangements for semiconductors utilizing a direct copper bonded (DCB) alumina substrate, which forms the base of the package (col. 1, lines 7-8 and 13-15). Dickenson brazes a copper tube 6 to a copper layer 2 of the thin sheet 1 of alumina. An external electrical connection 8 can then be made to the copper layer 2 by soldering the connection 8 to the copper tube 6. This arrangement overcomes two problems. First, the arrangement provides the advantage of making the external electrical connections 8 to the copper layer 2 “by soldering at a late stage of manufacture, when space over the substrate is no longer required for positioning and mounting the components on the substrate.” (Col. 2, lines 46-51). Second, the arrangement overcomes fatigue problems that would occur if the wires of the connection 8 were soldered directly to the copper layer 2, due to different thermal expansion rates between the copper layer 2 (lower due to the bond to alumina) and the wires of the connection 8 (col. 1, lines 32-34). The brazed connection between the copper tube 6 and the copper layer 2 is not susceptible to the fatigue that would occur in a solder joint between the copper layer 2 and a copper wire.

There is no motivation to modify the device of Dickenson into that of the pressure sensor device of Itoigawa, or modify the device of Itoigawa to include the mounting arrangement of Dickenson. The pressure sensor chip 6 of Itoigawa utilizes a bonding wire 11 to couple a pad of the chip 6 to a pad of the substrate 7 (col. 3, lines 48-49). The area surrounding the chip 6, bonding wire 11 and the substrate 7 is silicon gel (col. 3, lines 55-58). Accordingly, the chip 6 of Itoigawa does not have additional layers of structure that could obscure the pad of the sensor chip 6 at some late stage of manufacture. As a result, the pressure sensor chip of Itoigawa does not have the problem that the circuitry of Dickenson has: the need to access the circuitry at a late stage of the manufacturing process after the circuitry has been encumbered by other components.

Additionally, the second problem solved by Dickenson relating to the electrical connection to a copper layer that is bonded to an alumina substrate, does not apply to the pressure sensor chip 6 of Itoigawa. The device of Itoigawa is not disclosed as having a DCB alumina substrate or, more particularly, that the pad of the pressure sensor chip 6 is a copper layer of a DCB alumina substrate.

Thus, even this problem solved by Dickenson is not present in the pressure sensor chip 6 of Itoigawa.

Therefore, one skilled in the art would not be motivated to modify the circuitry of Dickenson to be the pressure sensor chip of Itoigawa or, stated another way, modify the pressure sensor chip of Itoigawa to include the tube 6 of Dickenson, because the pressure sensor chip of Itoigawa has no need for the connection arrangement disclosed by Dickenson. The addition of the tube 6 of Dickenson to the pressure sensor chip 6 of Itoigawa would only result in unnecessarily increasing the complexity of the pressure sensor chip, something a person having ordinary skill in the art would clearly avoid. Further, such a modification to the pressure sensor chip of Itoigawa would likely render the pressure sensor chip inoperable for its intended purpose.

For at least these reasons, claim 277 is non-obvious in view of Dickenson and Itoigawa. Withdrawal of the rejection is respectfully requested.

Claims 288 and 291-301 are believed to be allowable in view of the cited references at least due to their dependence from claim 277. Additional grounds for withdrawing the rejections of some of the dependent claims are provided below.

With regard to claims 293-296 and 298-301, Applicant submits that the a *prima facie* case of obviousness has not been established against the claims. In particular, each of the claims includes elements that are not taught by the cited references. For instance, neither Dickenson nor Itoigawa disclose “wherein the sensor comprises a chemical sensor” (claim 293), “an electrode, adapted to sense electrical activity in tissue of the patient” (claim 294), “a temperature sensor” (claim 295), “a flow sensor, adapted to sense a flow of blood in a vicinity of the apparatus” (claim 296), “a stimulating electrode” (claim 298), “a light source adapted to facilitate photodynamic therapy” (claim 299), “an electroactive polymer” (claim 300) or “a mechanical actuator” (claim 301). Accordingly, each of the claims is non-obvious in view of the cited references at least because they fail to disclose all of the elements of the claims.

In Section 8 of the Office Action, the Examiner rejected claims 279 and 317 under 35 U.S.C. § 103(a) as being unpatentable over Dickenson in view of Itoigawa, and further in view of

Woodard (U.S. Patent No. 5,984,711). Applicant respectfully believes that the rejections can be withdrawn for the reasons set forth below.

In rejecting claims 279 and 317, the Examiner found that neither Dickenson nor Itoigawa teach a hollow tube that is crimped to the lead wire as provided in claims 279 and 317. However, the Examiner found Woodard to disclose a catheter 10 comprising crimping a hollow tube 30 (conductive tube) that is crimped to a lead wire 16 (electrode wire) so as to be mechanically coupled thereto (col. 4, lines 27-34). The Examiner concluded that it “would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Conrad’s tube 80 to be crimped to the lead wire 76 in order to provide improved connection between a wire from an electrophysiology device, such as Conrad’s implantable thermometer catheter, and a conventional wire leading to external circuitry (see col. 2, lines 15-44).”

Applicant believes that there are two inadvertent errors in the rejections. First, the Examiner identified U.S. Patent No. 5,851,226 as corresponding to Woodard. However, that patent number corresponds to Skubitz et al. Applicant presumes that the Examiner intended to cite Woodard in making the rejection. Second, Applicant believes that the Examiner’s statement regarding the motivation to “modify Conrad’s tube 80” was intended to express the motivation to modify the tube 6 of Dickenson. Applicant’s remarks provided below will be in accordance with this understanding of the rejections.

Woodard is directed to methods and apparatus for connecting relatively small wires to standard size electrical connectors (Abstract). In particular, Woodard provides a solution to the problem of making electrical connections to very small electrode wires that extend from the catheter at a proximal end (col. 3, line 66-col. 4, line 8). Woodard’s solution to this problem is to attach an enlarged connector lead 26 to the proximal end of the electrode wires to expand the size of the proximal end of the electrode wires in order to facilitate an electrical connection between the lead 26/electrical wires and standard electrical connectors and/or wire, such as in a range from about 24 gauge to about 28 gauge (col. 4, lines 9-20).

There are several distinctions that can be made between the teachings of Woodard and the embodiments of the invention provided in claims 279 and 317. In Woodard, the conductive tube 30

is not directly soldered to implantable circuitry, as provided in claims 279 and 317. In fact, Woodard does not disclose the implantation of the conductive tube 30 of the lead 26 in a patient. Rather, the lead 26 extends outside of the lumen 22 of the catheter, which is inserted in the patient.

Additionally, the crimping of the conductive tube 30 onto the electrode wire 16 does not operate to make an electrical connection between the wire 16 and implantable circuitry. Rather, the crimping of the conductive tube 30 to the wire 16 merely operates to expand the size of the end of the wire 16 to facilitate its attachment to standard electrical connectors. This is a significant difference from the embodiments of the invention described in claims 279 and 317. In particular, the crimping of the hollow tube to the lead wire operates to make an electrical connection between the lead wire and the implantable circuitry.

Accordingly, none of the cited references disclose the direct attachment of a hollow conductive tube to implantable circuitry or the crimping of the hollow conductive tube to a lead wire to facilitate an electrical connection between the lead wire and the implantable circuitry. Accordingly, claims 279 and 317 are non-obvious in view of the cited references. Accordingly, Applicant believes that the rejections can be withdrawn.

In Section 9 of the Office Action, the Examiner rejected claims 280-285, 289 and 290 under 35 U.S.C. §103(a) as being unpatentable over Dickenson in view of Itoigawa and further in view of Skubitz et al. (U.S. Patent No. 5,851,226). Applicant respectfully believes that each of the rejected claims are non-obvious in view of the cited references for at least the reasons set forth above with regard to claim 277, from which they depend.

In Section 10 of the Office Action, the Examiner rejected claim 286 under 35 U.S.C. §103(a) as being unpatentable over Dickenson and Itoigawa and further in view of Delfino et al. (U.S. Patent No. 6,129,658). Applicant respectfully believes that the rejection can be withdrawn for the reasons set forth below.

In rejecting claim 286, the Examiner found col. 2, lines 35-36 of Delfino et al. to disclose that "metal-phosphate coating processes using phosphoric acid solutions are also known for

depositing coatings of to [sic.] prevent corrosion, lubricate, prolong the life of metal surfaces, and improve paint coating adhesion. Based on this disclosure, the Examiner concludes that "Delfino teaches using phosphoric acid solutions for treating implantable medical apparatuses". Applicant respectfully disagrees with this finding. The entire paragraph that includes the above cited section of Delfino et al. reads as follows:

"Metal-phosphate coating processes using phosphoric acid solutions are also known for depositing coatings of to prevent corrosion, lubricate, prolong the life of metal surfaces, and improve paint coating adhesion. However, they have not been found well-suited to the specialized needs of medical applications such as stents or stent materials. Briefly described, the metal surface chemically reacts with a phosphate solution, forming a phosphate layer on the metal's surface, which is either amorphous or crystalline depending on the operating conditions. A disadvantage of this coating technique is that the phosphate coating does not have the structural integrity required in medical uses and the has undesirable degrading or flaking characteristics. In addition, the transition metal (abbreviated herein as "m") phosphate coating is generally a primary (i.e., $mH_{sub.2}PO_{sub.4}$), secondary (i.e., $m_{sub.2}HPO_{sub.4}$), or tertiary (i.e., $m_{sub.3}PO_{sub.4}$) metal phosphate, all of which are often hydrated (i.e., $m_{sub.3-n}H_{sub.n}PO_{sub.4} \cdot xH_{sub.2}O$, where $x=1, 2, 3, \dots$)."

Clearly, Delfino et al. do not teach the use of phosphoric acid solutions for treating implantable medical apparatuses, as the Examiner contends. Rather, Delfino et al. appear to teach away from the use of phosphoric acid solutions in the treatment of implantable medical apparatuses. Therefore, claim 286 is non-obvious in view of the cited references.

Conclusion

In view of the above comments and remarks, Applicant respectfully believes that the present application is in condition for allowance. Reconsideration and favorable action is respectfully requested.

The Director is authorized to charge any fee deficiency required by this paper or credit any overpayment to Deposit Account No. 23-1123.

Respectfully submitted,

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